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| 10/697,264 | 10/31/2003 | Hipolito Carmelo Maria Barreiro | 36940-197982 | 9206 |

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| EXAMINER | |
|---|---|
| MINNIFIELD, NITA M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/697,264 | BARREIRO, HIPOLITO CARMELO MARIA | |
| | Examiner | Art Unit | |
| | N. M. Minnifield | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *13-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892) 4pgs.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's preliminary amendment filed October 31, 2003 is acknowledged and has been entered. Claims 1-12 have been canceled. New claims 13-29 have been added and are now pending in the present application.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims, 13-16, are directed to a pharmaceutical composition comprising polysaccharide from a gram-negative bacteria (*Pseudomonas aeruginosa*), water soluble thymus extract, water soluble prostate extract, and carbohydrates in a physiologically acceptable solvent and this composition is used for the treatment of benign prostate hyperplasia. Claims, 17-27 and 29, are directed to methods of preparing a pharmaceutical composition comprising polysaccharide from a gram-negative bacteria (*Pseudomonas aeruginosa*), water soluble thymus extract, water soluble prostate extract, and carbohydrates in a physiologically acceptable solvent. Claim 28 is directed to a method of treating benign prostatic hyperplasia comprising administering to an organism in need thereof a pharmaceutical composition comprising polysaccharide from a gram-negative bacteria (*Pseudomonas*

*aeruginosa*), water soluble thymus extract, water soluble prostate extract, and carbohydrates in a physiologically acceptable solvent.

There is no written description in the specification or the claims teaching or disclosing the source of the *water soluble thymus extract* or how it is isolated. There is no written description in the specification or claims teaching or disclosing the source of the *water soluble prostate extract* or how it is isolated. Does the thymus extract and prostate extract come from a human source or an animal source? Since the specification does not teach one of skill in the art, via a written description, how these two components of the claimed pharmaceutical composition were obtained, the source, how they were isolated and how they were prepared for use as part of the pharmaceutical composition, the claimed invention is not enabled.

The specification teaches and is enabled with regard to the method of treatment of benign prostate hyperplasia in a human wherein a pharmaceutical composition has been administered to the human. However, the specification does not teach the source of the water soluble thymus extract or the water soluble prostate extract, which are claimed components of the administered pharmaceutical composition, as previously stated. The specification has not completely taught how to make the claimed pharmaceutical composition because the specification has not taught one of skill in the how to obtain certain components of the claimed pharmaceutical composition.

The written description requirement has several policy objectives. ''[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is

"claimed." Another objective is to put the public in possession of what the applicant claims as the invention. The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. However, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately

described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

Again, there is no written description in the specification or the claims teaching or disclosing the source of the *water soluble thymus extract* or how it is isolated. There is no written description in the specification or claims teaching or disclosing the source of the *water soluble prostate extract* or how it is isolated.

4. The disclosure is objected to because of the following informalities: 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: There are several instances in the specification where the statements are not clear to the Examiner. It is not clear what Applicant means or intends. For example, at page 5, line 2, what is cheolids; page 5, line 3, does Applicant mean "booster" for the word "buster"? At page 6, line 5 there is a question mark in the middle of the sentence. At page 7, line 9, what does "(AND & ARN)" mean? Does Applicant mean DNA & RNA? At

page 8, line 6, what does Applicant mean by "into de resistance"? At page 9, line 14, what does Applicant mean by "P:P:A"? Does Applicant mean "P.P.A." as is recited on page 8? At page 9, line 18, what does Applicant mean by "focuses"? The bibliography set forth on pages 10-12 of the specification should provide complete reference citations. Further, there are references (27) to (30) that are cited else where in the specification (see pages 22-24) that should be added to the bibliography section found on pages 10-12. At page 12, line 8, does Applicant intend "Gram Negative Germ" to be Gram Negative Bacteria? What is the optimum concentration of the phenol solution described on page 14 of the specification? What does Applicant intend by "(days 21 & ?)" and "(days 16 & ?)" found on page 19, lines 4 and 5 respectively? The specification at pages 17-18 recites "gammas", does Applicant intend –grams--? On page 23 "conlussions", should be –conclusions--. On page 13 of the specification what does Applicant mean by the recitation of "establish la bacterial"? On page 5 of the specification, does Applicant mean "keloids" for "cheloids"? It is noted that there are other informalities that need to be corrected in this specification. Applicant is encouraged to review the specification carefully and make all appropriate corrections. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

5. The use of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to

prevent their use in any manner, which might adversely affect their validity as trademarks.

6. Claim 28 is objected to because of the following informalities: lines 5 and 6 are duplicative of lines 3-4 of this claim. Appropriate correction is required.

7. Claims 17-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 20-23 are vague and indefinite in the recitations of "high concentration" and "optimum culture time". What does Applicant intend by these phrase? Neither the claims nor the specification define the metes and bounds of a "high concentration" or a "optimum culture time". Claims 21-23 are vague and indefinite in the recitation of "conditioning a bacterial mass"; what does Applicant intend? Claims 21-23 lack antecedent basis in the recitation of "said washing and conditioning a bacterial mass". Claim 23 is vague and indefinite in the recitation of "said bacterial mass is bacteria free". How is a bacterial mass free from bacteria? Claim 28 is vague and indefinite in the recitation "of treating benign prostatic hyperplasia". Is this treatment for an organism and what is the scope of the "organism" (in vitro, in vivo, ex vivo, cells in culture, animal or human subject) recited in line 2 of the claim? Claims 17-27 and 29 are vague and indefinite in the recitation of "rigorous conditions of bacteriological asepsis"; what does Applicant intend? Claims 17-27 and 29 are vague and indefinite in the recitation of bacterial culture typified by biochemical tests"; what does Applicant intend ? What biochemical tests are performed? Claims 17-27 and 29 are vague and indefinite because it is not clear from the

preamble what the pharmaceutical composition contains. What are the components of the pharmaceutical composition? Claim 19 lacks positive antecedent basis in the recitation of "culture stock". Claim 20 is vague and indefinite in that it is not clear where this step should occur in the method of claim 17. Claim 22 lacks positive antecedent basis in the recitation of "said bacterial mass". Claim 22 is vague and indefinite in that it is not clear where this step should occur in relation to the method steps of claim 17 and 21. Claim 23 is vague and indefinite in that it is not clear where this step should occur in relation to the method steps of claim 17 and 21. Claims 26 and 27 are vague and indefinite in that it is not clear where these steps should occur in relation to the method steps of claim 17 and 24.

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
February 16, 2006